SCREENING OF NEWBORNS FOR NEONATAL HYPOTHYROIDISM (TUN/6/005) E1

CORE FINANCING

YEAR	Experts		Equipment	Fellowships		Scientific Visits		Training	Sub-contracts	Misc. Comp.	Total
	m/d	US $	US $	m/d	US $	m/d	US $	US $	US $	US $	US $
1995	-	-	15,000	-	-	-	-	10,000	-	-	25,000
1996	-	-	15,000	-	-	-	-	10,000	-	-	25,000

First Year Approved: 94 Total expenditure to 30 September 1994: $13,308 (TACF)

OBJECTIVES: To establish a network for screening every newborn child in Tunisia for neonatal hypothyroidism, and for prompt treatment of those cases in which a positive result is obtained to prevent the development of sequelae such as mental retardation.

BACKGROUND: Thyroid deficiency in newborns is most prevalent in areas of endemic iodine deficiency, which is common in developing countries. In the most serious cases, the condition can lead to irreversible neurological impairment or deaf mutism, but varying degrees of mental and intellectual empairment results even when the lack of iodine is less severe. The condition is treatable provided that it is detected within the first few days of life. This is best accomplished by measurement of the thyroid related hormones in the infant's blood by radioimmunoassay (RIA) methods, which are simple and inexpensive enough to be applied on a national scale. For a national screening programme to be established and succeed, RIA laboratories must exist, or be created, in a sufficient number of centres to provide reasonable coverage for the entire country. Ideally, the centres would be located in major hospitals so that not only would the newborn infants be readily available for testing, but the chances of prompt and efficient treatment with hormonal replacement would also be high, and the smallest number of cases would be lost to follow-up. Tunisia has RIA facilities in at least nine major hospitals, each with adequate equipment and trained staff. The Agency has provided extensive support to these centres under the regional project RAF/6/007 and national projects. As a result, inexpensive bulk reagent based methods have been introduced in all centres. In addition, the capability for production and distribution of the primary reagents needed has been established at the Salah Azaiz Institute in Tunis, which also has the data processing capability necessary for analysis of test results on a national scale.

PROJECT PLAN: The Salah Azaiz Institute will be established as the principal centre for the screening programme, with prime responsibility for reagent production and distribution to other centres, or user laboratories, capable of carrying out the tests. The user laboratory in each area would receive samples by post or other means from smaller units such as maternity hospitals, primary health centres in villages, or even from public health workers or midwives, and carry out the analysis. An EQAS will be operated in order to ensure reliability of the results. Each laboratory will have its own internal quality control procedures as a part of standard RIA practice. The Salah Azaiz Institute will also be responsible for organizing and implementing the required training programme on the methodology and management of the operations in the user laboratories. The total estimated cost of the project in Tunisia, which would be carried out over a period of three years, is $100,000.

NATIONAL COMMITMENT: The Government will continue to support the established RIA laboratories and the Salah Azaiz Institute. Once the national programme is established, the Government would provide the support necessary to sustain the screening operation indefinitely.

AGENCY INPUT: Training, reagent supplies, and minor equipment such as a magnetic separator.

IMPACT: Neonatal hypothyroidism can occur as frequently as once in each 1000 live births. One technician working full time on the analysis of blood spot samples can realistically be expected to handle 15,000 samples per year. Thus, if all the existing RIA centres participate, the total sample capacity of over 100,000 can be achieved. The economic cost of the screening programme envisaged is insignificant compared to that of maintaining even a few severely mentally retarded, socially unproductive individuals requiring institutional care. The prevention of personal and family anguish is an added social benefit.